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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/630,572      | 07/30/2003  | Alfred Wong          | 013860-000002       | 8250             |

7590 04/21/2004  
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EXAMINER

NUTTER, NATHAN M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1711

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/630,572

Applicant(s)

WONG ET AL.

Examiner

Nathan M. Nutter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 5, the term "like" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "like"), thereby rendering the scope of the claim unascertainable. The Specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claim is indefinite as to the solvent used for washing and filtering. See MPEP § 2173.05(d).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al (U.S. Patent 4,076,700) taken with Harada et al (U.S. Patent 3,877,537), Malik et al (CS 256092, English translation) and Eastman Kodak (GB 895, 145).

The reference to Harada et al teaches the isolation of a crystalline phytosterol derived from tall oil by a) converting steryl esters to free phytosterol, b) distilling the pitch to remove water and the lighter phase, c) distilling the bottom fraction to obtain a fraction containing free phytosterol, d) dissolving the free phytosterol-containing fraction in isopropanol and water, and e) recrystallizing the phytosterol. Note column 11 (line 45) to column 12 (line 12) and column 17 (line 65) to column 18 (line 10) for these teachings. It is well-known in the art that a recrystallization step includes a washing of the crystalline product. The reference fails to teach specifically that the starting material may comprise tall oil pitch, or neutralization of the saponified pitch before distillation, or the necessary conditions for the distillation and saponification steps.

Harada et al ('537) teach that a free phytosterol-containing fraction may be obtained similarly from tall oil pitch. Specifically, tall oil pitch is treated with aqueous sodium hydroxide (8% by weight of the tall oil pitch) at 180°C for 50 minutes. Subsequently the lighter end is removed and the phytosterol-containing fraction is obtained through distillation. Note column 5 (line 45) to column 6 (line 6) it is well known in the art that the lack of the acidulation of the saponified pitch renders most of the fatty acids contained therein non-distillable. Note column 12 (lines 13-30). The fatty acids become distillable after an acidulation step, and

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therefore the phytosterol-containing fraction would have less fatty acid. The reference to Eastman Kodak teaches that phytosterol may be crystallized from a mixture of phytosterol and fatty acid. Note page 2 (lines 95-103) and page 3, example 1. The reference to Malik et al teaches that distillation may be used to purify phytosterol from saponified tall oil pitch that has been acidified before the distillation. Note the second paragraph at page 1 of the English translation.

Therefore, it would have been *prima facie* obvious to an artisan having an ordinary skill in the art, at the time the invention was made, to modify the method of Harada et al ('700) using the tall oil pitch as the starting material because it is known that the phytosterol-containing distilling fraction may be similarly obtained from tall oil pitch as shown by Harada et al ('537). The acidulation of the saponified tall oil pitch before the distillation is deemed to be obvious because it is known that phytosterol may be crystallized from a mixture of phytosterol and fatty acid, as taught by the reference to Eastman Kodak. The employment of the acidulation step is further obvious because it is known that phytosterol may be purified from fatty acids by optimization of the distillation conditions, i.e. temperature and pressure. Note Malik et al. The optimization of result effective parameters, i.e. temperature and time for saponification and temperature and vapor pressure for distillation, and the re-crystallization conditions, are considered to be within the skill of an artisan. Note *In re Boesch and Slaney* (CCPA) 204 USPQ 215. the employment of the various acids for acidulation is seen to be a selection from amongst equally suitable materials and, as such, obvious to a practitioner. Note *Ex parte Winters* 11 USPQ 2<sup>nd</sup> 1387. A further

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distillation of the phytosterol-containing fraction for purity, as recited in instant claim 22, is seen to be obvious since it is known that phytosterols may be purified through distillation.

The references to Robinson et al (U.S. Patent 6,057,462) and Schersl (U.S. Patent 6,465,665) are both cited of interest. The references both teach processes of isolation of phytosterols from tall oil pitch that differ patentably from that recited and claimed herein. Note the Abstracts of each. Neither document is deemed to present a bar to the patentability of the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan M. Nutter whose telephone number is 571-272-1076. The examiner can normally be reached on Monday-Friday 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James J. Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Nathan M. Nutter", with a long horizontal flourish extending to the right.

Nathan M. Nutter  
Primary Examiner  
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nmn

18 April 2004